



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

Mr. Andrew J. Lane
Lane Labs-USA, Inc.
110 Commerce Drive
Allendale, New Jersey 07401

MAR 18 1999

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Dear Mr. Lane:

This is in response to your letter of February 4, 1999, to the Food and Drug Administration (FDA) pursuant to 21 U.S.C 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Lane Labs-USA, Inc. is marketing the dietary supplement "ImmunoFin" labeled with the claim "be prepared for cold and flu season."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate disease, namely the common cold and influenza. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, New Jersey District Office, Office of Compliance, HFR-MA340

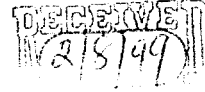
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February 4, 1999

Food & Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street SW
Washington, DC 20204



Dear Sirs:

Notice is hereby given pursuant to the requirement of section 403(r)(6)(21 U.S.C. 343(r)(6)) of the Federal Food, Drug and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93 that LANE LABS USA, Inc. 110 Commerce Drive, Allendale, NJ 07401 is marketing a dietary supplement bearing the following statements(s) on the label and/or in the labeling:

TEXT OF CLAIM:

"Be Prepared for Cold and Flu Season"

NAME OF INGREDIENT

Shark Liver Oil

NAME OF SUPPLEMENT

ImmunoFin

I certify that the information contained in this notice is complete and accurate and that LANE LABS USA, INC. has substantiation that the statement is truthful and not misleading.

Sincerely,

Andrew J. Lane

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